Docket No. 17618CON7B (AP)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Acheampong, *et al.*	Examiner: TBA
Serial No.: TBA	Group Art Unit: TBA
Filed: Herewith	Confirmation No. TBA
For: METHODS OF PROVIDING THERAPEUTIC EFFECTS USING CYCLOSPORIN COMPONENTS	Customer No.: 51957

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Prior to examining the above-referenced application, please amend the specification as described on page 2 of this paper, and please amend the claims as described on pages 3-6 of this paper. Remarks follow on page 7.

Amendments to the Specification

Please replace page 1, lines 5-10 of the specification filed herewith with the following amended paragraph:

This application is a continuation of copending U.S. Application Serial No. 13/961,835 filed August 7, 2013, which is a continuation of copending U.S. Application Serial No. 11/897,177, filed August 28, 2007, which is a continuation of U.S. Application Serial No. 10/927,857, filed August 27, 2004, now abandoned, which claimed the benefit of U.S. Provisional Application No. 60/503,137 filed September 15, 2003, which ~~is~~ are incorporated in ~~its~~ their entirety herein by reference.

Please replace page 4, line 25 – page 5, line 3 of the specification filed herewith with the following amended paragraph:

The present methods are useful in treating any suitable condition which is therapeutically sensitive to or treatable with cyclosporin components. Such conditions preferably are ophthalmic or ocular conditions, that is relating to or having to do with one or more parts of an eye of a human or animal. Included among such conditions are, without limitation, dry eye syndrome, phacoanaphy1actic endophthalmitis, uveitis, vernal conjunctivitis, atopic keratoconjunctivitis, corneal graft rejection and the like conditions. The present invention is particularly effective in treating dry eye syndrome. Cyclosporin has been found as effective in treating immune mediated keratoconjunctivitis sicca (KCS or dry eye disease) in a patient suffering therefrom. The activity of cyclosporins is as an immunosuppressant and in the enhancement or restoring of lacrimal gland tearing. Other conditions that can be treated with cyclosporin components include an absolute or partial deficiency in aqueous tear production (keratoconjunctivitis sicca, or KCS). Topical administration to a patient's tear deficient eye can increase tear production in the eye. The treatment can further serve to correct corneal and conjunctival disorders exacerbated by tear deficiency and KCS, such as corneal scarring, corneal ulceration, inflammation of the cornea or conjunctiva, filamentary keratisis, mucopurulent discharge and vascularization of the cornea.

Amendments to the claims

The following list of claims will replace all previous versions of claims presented in this application:

1. – 36. (Canceled)

37. (New) A method of increasing tear production in the eye of a human, the method comprising topically administering to the eye of the human an emulsion at a frequency of twice a day, wherein the emulsion comprises cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, Pemulen, water, and castor oil in an amount of about 1.25% by weight; and

wherein the topical ophthalmic emulsion is effective in increasing tear production.

38. (New) The method of Claim 37, wherein the emulsion further comprises a tonicity agent or a demulcent component.

39. (New) The method of Claim 38, wherein the tonicity agent or the demulcent component is glycerine.

40. (New) The method of Claim 37, wherein the emulsion further comprises a buffer.

41. (New) The method of Claim 40, wherein the buffer is sodium hydroxide.

42. (New) The method of Claim 37, wherein the topical ophthalmic emulsion further comprises glycerine and a buffer.

43. (New) The method of Claim 37, wherein the emulsion comprises polysorbate 80 in an amount of about 1.0% by weight.

44. (New) The method of Claim 37, wherein the emulsion comprises Pemulen in an amount of about 0.05% by weight.

45. (New) The method of Claim 37, wherein the emulsion further comprises glycerine in an amount of about 2.2% by weight and a buffer.

46. (New) The method of Claim 45, wherein the buffer is sodium hydroxide.

47. (New) The method of Claim 37, wherein, when the emulsion is administered to an eye of a human in an effective amount in treating KCS, the blood of the human has substantially no detectable concentration of cyclosporin A.

48. (New) The method of Claim 42, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.

49. (New) The method of Claim 37, wherein the emulsion is as substantially therapeutically effective as an emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

50. (New) The method of Claim 37, wherein the emulsion achieves at least as much therapeutic effectiveness as an emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

51. (New) The method of Claim 37, wherein the emulsion breaks down more quickly in the eye of a human, once administered to the eye of the human, thereby reducing vision distortion in the eye of the human as compared to an emulsion that contains only 50% as much castor oil.

52. (New) The method of Claim 37, wherein the emulsion, when administered to the eye of a human, demonstrates a reduction in adverse events in the human, relative to an

emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

53. (New) The method of Claim 52, wherein the adverse events include side effects.

54. (New) A method of treating KCS, the method comprising the step of topically administering to an eye of a human an emulsion at a frequency of twice a day, the emulsion comprising:

cyclosporin A in an amount of about 0.05% by weight;

castor oil in an amount of about 1.25% by weight;

polysorbate 80 in an amount of about 1.0% by weight;

Pemulen in an amount of about 0.05% by weight;

a tonicity component or a demulcent component in an amount of about 2.2% by weight;

a buffer; and

water;

wherein the emulsion is effective in treating KCS.

55. (New) The method of Claim 54, wherein the buffer is sodium hydroxide.

56. (New) The method of Claim 54, wherein the tonicity component or the demulcent component is glycerine.

57. (New) The method of Claim 54, wherein, when the emulsion is administered to the eye of a human in an effective amount in treating KCS, the blood of the human has substantially no detectable concentration of the cyclosporin A.

58. (New) The method of Claim 54, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.

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